IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

PURDUE PHARMA L.P., THE P.F. LABORATORIES, INC., PURDUE PHARMACEUTICALS L.P. and RHODES TECHNOLOGIES, Plaintiffs, v. COLLEGIUM PHARMACEUTICAL, INC., Defendant.	)	C.A. No. 15-cv-13099-FDS (Lead Docket No.)

DEFENDANT COLLEGIUM PHARMACEUTICAL, INC.'S MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION FOR PARTIAL JUDGMENT ON THE PLEADINGS PURSUANT TO FED. R. CIV. P. 12(c) AND FOR ENTRY OF FINAL JUDGMENT PURSUANT TO FED. R. CIV. P. 54(b)

Collegium Pharmaceutical, Inc. ("Collegium") respectfully submits this brief in support of its motion for partial judgment on the pleadings. Specifically, Collegium respectfully requests that the Court enter judgement of invalidity of U.S. Patent Nos. 7,674,799 (the "'799 patent"), 7,674,800 (the "'800 patent"), and 7,683,072 (the "'072 patent") (collectively, "the listed patents") based on collateral estoppel. Plaintiffs admit in the Complaint that the patents have been finally adjudged invalid in a prior action to which Plaintiffs were parties.

I. INTRODUCTION

This is a straightforward case for the application of collateral estoppel. After years of litigating in the Southern District of New York, more than 25 lawsuits, and a three-week bench trial, the Southern District of New York found the listed patents invalid as obvious in *Purdue Pharma L.P., et al. v. Teva Pharmaceuticals, USA, Inc.*, 994 F. Supp. 2d 367 (S.D.N.Y. 2014) ("the New York Action"). Plaintiffs explicitly admit the prior judgment of invalidity in the

Complaint. (D.I. 1 at ¶ 1).The New York Action involved the same plaintiffs, the same patents, and the same issues of invalidity with respect to the listed patents.

Plaintiffs Purdue Pharma L.P., The P.F. Laboratories, Inc., Purdue Pharmaceuticals, L.P. and Rhodes Technologies (collectively, "Purdue") have asserted the invalid listed patents in an effort to invoke a barrier that prevents FDA from finally authorizing the marketing, sale and delivery of Collegium's product to healthcare providers until this Court formally enters final judgment of invalidity as to the listed patents. As discussed in Collegium's concurrently filed motion to expedite, an FDA advisory committee identified Collegium's proposed product as "very promising" and a "step forward from the available products" in treatment of chronic pain because of its heightened abuse-deterrent properties—including as compared to Purdue's OxyContin®. Accordingly, for the reasons stated below, Collegium respectfully requests that the Court grant Collegium's motion for partial judgment on the pleadings of invalidity of the three listed patents based on collateral estoppel. In addition, Collegium requests that, pursuant to Fed. R. Civ. P. 54(b), the Court enter final judgment of invalidity of the listed patents.

II. BACKGROUND INCLUDING UNDISPUTED FACTS FOUND IN THE PLEADINGS OR CONTAINED IN THE JUDGMENT IN THE PRIOR ACTION

This case arises under the Hatch-Waxman statutory scheme governing patent actions involving drugs. (D.I. 1 at ¶ 1). Under the Hatch-Waxman statute, a party that files a New Drug Application ("NDA") or an Abbreviated New Drug Application ("ANDA") can be accused of infringing patents listed in FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") as covering the Reference Listed drug product in the NDA or ANDA. 35 U.S.C. § 271(e)(2)(A). According to the statutory scheme, FDA is not permitted to grant final approval to market the drug that is the subject of the accused NDA or ANDA until (1) 30 months have passed since filing suit ("30-month stay"), or (2) *the district court enters final*

judgment of invalidity or non-infringement. 21 U.S.C. § 355(c)(3)(C). A plaintiff is only entitled to the 30-month stay based on patents listed in the Orange Book and only if they are not determined to be invalid or not infringed by a district court.

In this case, Collegium filed NDA No. 208090 to obtain approval to market its novel, abuse-deterrent formulation of oxycodone. (D.I. 18, Counterclaim ¶ 11). As required by the statute, Collegium provided a Paragraph IV Notice detailing the factual and legal bases for why no valid claim of the listed patents are infringed by the commercial manufacture, use or sale of the Collegium's proposed product. (D.I. 18, Counterclaim ¶¶ 17-18). Purdue lists 13 patents in the Orange Book as covering OxyContin®. Purdue asserts that only the three of those patents would be infringed by Collegium's proposed product. All three of those patents, however, were invalidated by Judge Stein of the Southern District of New York.[1] A final judgment as to those three listed patents in this case is the only thing that stands in the way of Collegium receiving final approval from FDA to market, sell, and distribute its novel, abuse-deterrent formulation of oxycodone.

As mentioned above, the three listed patents were the subject of prior litigations in the Southern District of New York. After a three-week bench trial in the lead case, the Southern District of New York issued a decision invalidating the three listed patents (that decision refers to the listed patents as the Low-ABUK patents). *See Purdue Pharma L.P., et al. v. Teva Pharmaceuticals, USA, Inc*., 944 F. Supp. 2d 367; 1:11-cv-02037-SHS (D.I. 149) (S.D.N.Y. 2014) (attached hereto as Exhibit A). Based on its decision in the Teva case, the Southern

[1] Purdue has also accused Collegium of infringing U.S. Patent No. 8,652,497 (D.I. 1 at ¶ 47). That patent is not listed in the Orange Book and was not previously litigated. Because the '497 patent is not listed in the Orange Book, it cannot form the basis of a 30-month stay of FDA approval. Accordingly, if this Court grant's Collegium's motion for partial judgment on the pleadings, Collegium requests that the Court enter final judgment as to the listed patents pursuant to Fed. R. Civ. P. 54(b) and to order the '497 infringement and invalidity case to go forward.

District of New York entered judgment of invalidity based on collateral estoppel in other cases involving the listed patents. *See e.g. Purdue Pharma L.P., et al. v. Amneal Pharmaceuticals, LLC*, 11-cv-8153-SHS, D.I. 86 (S.D.N.Y. Jan. 29, 2014) (attached hereto as Exhibit B). In that proceeding, Purdue "agreed that collateral estoppel based on the *Teva* decision precludes Plaintiffs' claims for relief" in the other cases. *Id*. at p. 2. As such, in other cases, Purdue has admitted that collateral estoppel precludes its claim for relief for alleged infringement of the listed patents. Further, in the Complaint in this case, Purdue admitted that "these three patents [the listed patents] have been found infringed but invalid in a previous lawsuit not involving Collegium." (D.I. 1 at ¶ 1).

III. ARGUMENT

A. Legal Standard

"After the pleadings are closed—but early enough not to delay trial—a party may move for judgment on the pleadings." Fed. R. Civ. P. 12(c). "[T]he pleadings are closed for the purposes of Rule 12(c) once a complaint and answer have been filed." *McGuigan v. Conte*, 629 F. Supp. 2d 76, 80 (D. Mass. 2009) (quoting *Doe v. United States*, 419 F.3d 1058, 1061 (9th Cir. 2005)). A Rule 12(c) motion is treated much like a Rule 12(b)(6) motion, but because a Rule 12(c) motion is filed after the close of pleadings, it implicates the pleadings as a whole. *Aponte–Torres v. Univ. of Puerto Rico*, 445 F.3d 50, 55 (1st Cir. 2006); *Pérez–Acevedo v. Rivero–Cubano*, 520 F.3d 26, 29 (1st Cir. 2008). A motion for judgment on the pleadings is reviewed under the same standards as a motion to dismiss pursuant to Rule 12(b)(6). *Pérez–Acevedo*, 520 F.3d at 29.

Judgment under this rule is appropriate where, accepting all of the nonmovant's allegations set forth in its pleadings as true, and drawing all reasonable inferences in its favor, it appears "beyond a doubt that the nonmoving party can prove no set of facts in support of [its] claim

which would entitle [it] to relief." *Feliciano v. Rhode Island*, 160 F.3d 780, 788 (1st Cir. 1998). When ruling on a Rule 12(b)(6) motion to dismiss, a district court is "generally limited to considering 'facts and documents that are part of or incorporated into the complaint.'" *Giragosian v. Ryan*, 547 F.3d 59, 65 (1st Cir. 2008) (citation omitted). In reviewing a motion to dismiss, the Court may also consider some extrinsic documents, such as "documents the authenticity of which are not disputed by the parties; documents central to plaintiffs' claim; and documents sufficiently referred to in the complaint." *Curran v. Cousins*, 509 F.3d 36, 44 (1st Cir. 2007). The "Court's review is more expansive, however, where a motion to dismiss is premised on a defense of res judicata. Then, it may also take into account the record in the original action." *Silva v. City of New Bedford, Mass*., 677 F. Supp. 2d 367, 369 (D. Mass. 2009) (citing *Andrew Robinson Int'l, Inc. v. Hartford Fire Ins. Co*., 547 F.3d 48, 51 (1st Cir. 2008)).

"Issue preclusion (also called collateral estoppel) 'prevents a party from relitigating issues that have been previously adjudicated.'" *Manganella v. Evanston Inc. Co*., 700 F.3d 585, 591 (1st Cir. 2012) (citation omitted). Issue preclusion applies where "(1) the issues raised in the two actions are the same; (2) the issue was actually litigated in the earlier action; (3) the issue was determined by a valid and binding final judgment; and (4) the determination of the issue was necessary to that judgment." *Id*.

"[O]nce the claims of a patent are held invalid in a suit involving one alleged infringer, an unrelated party who is sued for infringement of those claims may reap the benefit of the invalidity decision under the principles of collateral estoppel." *Mendenhall v. Barber-Green Co.*, 26 F.3d 1573, 1577 (Fed. Cir. 1994) (citing *Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313 (1971)). "If an alleged infringer raises the defense of collateral estoppel, the burden is on the patentee 'to demonstrate, if he can, that he did not have a fair opportunity procedurally,

substantively and evidentially to pursue his claim the first time.'" *Miss. Chem. Corp. v. Swift Agric. Chems. Corp.*, 717 F.2d 1374, 1376 (Fed. Cir. 1983) (citation omitted). The Court's "inquiry into whether the plaintiff was afforded a full and fair opportunity to litigate is quite narrow and does not involve a judgment on the merits." *Pharmacia & Upjohn Co. v. Mylan Pharms., Inc.*, 170 F.3d 1373, 1380 (Fed. Cir. 1999).

B. Collegium is Entitled to a Partial Rule 12(c) Judgment On the Pleadings Based On Collateral Estoppel From New York Action

Purdue admits in the pleadings that the listed patents asserted in this case were invalidated in a final judgment of the New York Action. This is as straightforward of a case of collateral estoppel as they come. First, the issues raised in the two actions are the same. In both the New York Action and this case, the validity of the listed patents is at issue. Second, the issue of validity was actually litigated in the earlier action. In the New York action, the validity of the listed patents was tried in a three-week bench trial and Judge Stein of the Southern District of New York issued a 115-page decision setting forth findings of fact and conclusions of law in which he found the listed patents invalid. Third, the issue of validity was determined by a valid and binding final judgment. As noted above, Judge Stein entered final judgment of invalidity of the listed patents in the Teva case and entered final judgments of invalidity of the listed patents on the basis of collateral estoppel in related cases based on its final judgment in the Teva case. Further, in those cases, Purdue admitted that collateral estoppel of invalidity of the listed patents was appropriate. Finally, the determination of invalidity was necessary to that final judgment—the final judgment was of invalidity. It cannot be disputed that all four elements necessary to find collateral estoppel are present in this case and numerous courts have found collateral estoppel to apply in analogous cases. *See e.g. Mendenhall v. Barber-Green Co.*, 26 F.3d 1573, 1577 (Fed. Cir. 1994) (finding invalidity on the basis of collateral estoppel even where the invalidity

judgment was entered after the appeal of the second case); *Zoll Medical Corp. v. Philips Elecs. N.A. Corp.*, Civ. No. 14-10029-NMG, 2014 U.S. Dist. LEXIS 51251, **9-11 (D. Mass. Apr. 11, 2014) (dismissing a case on the basis of collateral estoppel based on a prior judgment of non-infringement by a related product); *Juxtacomm-Texas Software, LLC v. Lanier Parking Sys. of Va., Inc.*, 944 F. Supp. 2d 469 (E.D. Va. 2013) (granting a motion for judgment on the pleadings on the basis of collateral estoppel based on a prior judgment of invalidity for indefiniteness); *Galderma Labs. Inc. v. Amneal Pharmaceuticals, LLC*, 921 F. Supp. 2d 278 (D. Del 2012) (granting judgment on the pleadings of non-infringement based on collateral estoppel where the first case involved a product with a slightly different formulation than in the second case).

In addition, the fact that Purdue has appealed the decision in the New York Action is irrelevant. The pendency of an appeal does not diminish either the finality or binding effect of a trial court's holding. *See Pharmacia & UpJohn Co.*, 170 F.3d at 1381 (Fed. Cir. 1999); *see also Novo Nordisk, Inc. v. Paddock Labs., Inc.*, 797 F.Supp.2d 926, 934 (D. Minn. 2011) (entering final judgment of invalidity and unenforceability on the basis of collateral estoppel while an appeal of the original decision was pending and refusing to stay the litigation pending the appeal), *rev'd in part on other grounds* 515 Fed. App'x 889 (Fed. Cir. 2013). Accordingly Purdue's appeal of the New York Action decision does not preclude this Court from entering judgment of invalidity on the basis of collateral estoppel now.

C. Entry of Partial Final Judgment Pursuant to Rule 54(b) Is Appropriate in this Case.

Federal Rule of Civil Procedure 54(b) provides:

> When more than one claim for relief is presented in an action, . . . the court may direct the entry of a final judgment as to one or more but fewer than all of the claims or parties only upon an express determination that there is no just reason for delay and upon express direction for the entry of judgment.

Entry of final judgment is predicated on a two-step analysis. First, the district court must

determine that it is dealing with a final judgment. *Curtiss-Wright Corp. v. General Elec. Co.*, 446 U.S. 1, 7 (1980). A decision is a "judgment" if it is "a decision on a cognizable claim for relief," and a judgment is "final" if it is "an ultimate disposition of an individual claim entered in the course of a multiple claims action." *Id.* (quoting *Sears, Roebuck & Co. v. Mackey*, 351 U.S. 427, 436 (1956)). Second, the court must determine whether there is any just reason for delay. *Id.* at 8.

Whether there is any just reason for delay is similarly a two-step process. "First, the court examines the interrelationship between the legal and factual basis of the claims for which final judgment is being sought and the claims remaining in the case." *Navitag Techs., Inc. v. Silva*, 738 F. Supp. 2d 207, 210 (D. Mass. 2010) (citing *Maldonado-Denis v. Castillo-Rodriguez*, 23 F.3d 576, 580 (1st Cir. 1994). Second, the court must assess "the litigation as a whole, and a weighing of all factors relevant to the desirability of relaxing the usual prohibition against piecemeal appellate review in the particular circumstance." *Id*. (quoting *Spiegel v. Trustees of Tufts College*, 843 F.2d 38, 42 (1st Cir. 1988)).

In this case, there can be no doubt that if the Court finds the three listed patents to be invalid based on collateral estoppel that it is an ultimate disposition of an individual claim in this case. Purdue's complaint lists two separate claims for relief, the first being "Patent Infringement of the Improved API Patents." (D.I. 1 at ¶¶ 43-46). A finding of invalidity of the three listed patents would completely dispose of that claim for relief and thus constitutes a "final" judgment. Similarly, there is no just reason for delay. The patents that are the subject of this motion have no relation to the remaining patent—the technology is entirely different. As such, judgment as to the three listed patents will have no impact on adjudication of the '497 patent. Second, as explained in Collegium's concurrently filed motion to expedite, Collegium will be greatly prejudiced if this Court refuses to enter final judgment, whereas Purdue will not. Purdue already had a full and fair

opportunity to litigate the validity of the three listed patents. Purdue should not be permitted to maintain an action on the basis of invalid patents to keep Collegium off the market and to prevent patients from accessing a safe drug that fulfills and unmet need. The equities clearly favor entering final judgment in this case. *See e.g. Navitag Techs., Inc.* 738 F. Supp. 2d at 211 (finding that the equities favored entering partial final judgment where movant's business would suffer harm and defendant would suffer no prejudice).

IV. CONCLUSION

For the reasons set forth above, Collegium respectfully requests that the Court grant Collegium's motion for partial judgment on the pleadings. In addition, because time is of the essence, Collegium respectfully requests that, pursuant to Fed. R. Civ. 54(b), the Court enter final judgment of invalidity of U.S. Patent Nos. 7,674,799, 7,674,800, and 7,683,072.

Respectfully submitted,

Date: November 9, 2015

By */s/ Jake M. Holdreith*

Jake M. Holdreith (admitted *pro hac vice*)
Jamie R. Kurtz (admitted *pro hac vice*)
Kelsey J. Thorkelson (admitted *pro hac vice*)
Robins Kaplan LLP
2800 LaSalle Plaza
800 LaSalle Avenue
Minneapolis, MN 55402–2015
612–349–8500

Christopher P. Sullivan (BBO#485120)
Robins Kaplan LLP
800 Boylston Street
Suite 2500
Boston, MA 02199

Attorneys for Defendant Collegium Pharmaceutical, Inc.

CERTIFICATE OF SERVICE

I hereby certify that the foregoing document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) this 9th day of November, 2015.

/s/Jake M. Holdreith
Jake M. Holdreith (admitted *pro hac vice*)

CERTIFICATE OF CONFERENCE

I hereby certify that counsel for the parties named in this matter have met and conferred and have attempted in good faith to resolve or narrow the issue via telephone conference this 9th day of November, 2015.

/s/Jake M. Holdreith
Jake M. Holdreith (admitted *pro hac vice*)